25012021

EU-/FDA-Declaration of Compliance
„Food and pharmaceutical physiological harmless“

We confirm that the product

TEADIT Packing Type 2005

is suitable for use as a material or article for direct contact with food and active pharmaceutical ingredient and thus in the application in the pharmaceutical plant.

The product has been manufactured in accordance with the relevant requirements of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice.

The product complies with the relevant requirements as laid down in following regulations:

a) EU regulation

- EC Framework Regulation 1935/2004
- EU Regulation No 10/2011

b) USA regulation

- U.S. regulations 21 CFR 170.39

Overall migration
Migration tests were performed and have shown that under the test conditions the migration limits where not exceeded.

Specific migration limits (SML) and quantitative maximum (QM) or (QMA)
☐ Not applicable: Material does not contain substances subject to SML / QM / QMA.
☒ The following substances are subject to SML and/or QM or QMA limitations and/or specifications. The prescribed values are maintained under the test conditions.

Name of substance	Ref.	SML / QM / QMA
Barium sulphate	------	*SML 1,0 mg/kg*
Polyethylene glycol alcylether-oligomers	*77708 (EU 10/2011)*	*SML 1,8 mg/kg*
Perfluoro octanic acid (PFOA)	*EFSA*	*SML 90 µg/kg*

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Based on the screening results, including the analytical tolerance, the investigated sample is in compliance with the safety requirements of Article 3 of Regulation EC 1935/2004 for the intended use as stuffing box packing (**up to max. 200 °C) provided that the ratio between the contact area of the seal and the contact area of the sealed container is at least 1:1800.** In addition, the sample is in compliance with the safety requirements according to 21 CFR 170.39.

We do not use animal derived ingredients at production. The product is free of BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy).

This declaration of compliance is valid for the product delivered by us and as specified above. The information included in this document is valid for the stated revision versions and dates and/or until this document is superseded.

Because of possible changes in the underlying legislation and regulations, as well as possible changes in our products, we cannot guarantee that the status of this document will remain unchanged. We therefore recommend our customers to verify the regulatory status periodically. It will be renewed where the previous conformity is no longer ensured. It is the responsibility of the user to evaluate and determine the suitability of the material for any particular application.

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